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## Original Article

# Implementation of a risk management plan in a hospital operating room

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### ARTICLE INFO

#### Article history:

Received 22 December 2014

Received in revised form

30 October 2015

Accepted 30 October 2015

Available online 15 December 2015

#### Keywords:

Risk management

Operating room

Nursing

### ABSTRACT

A risk management program based on AS–NZS4360 risk management standards was developed and implemented in the operating room of Peking University Third Hospital. To accomplish this task, we developed a risk quantification matrix and a risk register form to identify potential risks in the operating room, and then implemented operating room policies designed to reduce or eliminate those risks. We also established a consultation mechanism and risk monitoring system designed to minimize risks to operation room nurses. Finally, we continuously seek to improve our operating room risk management capabilities, so we can continue to improve the quality of service provided and guarantee the safety of surgical patients.

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## 1. Introduction

In a medical marketplace with fierce competition, the implementation of risk management strategies has received increased attention by health care managers. Risk management refers to the management of emergencies which cannot always be anticipated in advance, but will cause serious consequences if they occur. The operating room is a key area of any hospital, and any negligence by operating room staff members can endanger a patient's life. Possible errors that can be made by operating room staff members include the failure to properly transport patients, faulty identification of a surgical site, an incorrect blood transfusion, the poor intra-operative management of surgical tools, placement of the patient in an incorrect operative position, inadequate anti-infective procedures, poor surgical record keep, and the

improper use of surgical equipment, such as a microtome. Due to the above risk factors, it is very important to strengthen the management of staff in an operating room by using risk management theory to analyze and deal with potential risks, and establish mechanisms for risk prevention and resolution [1]. This report describes using the AS–NZS4360 risk management standard to develop a risk management plan for the operating room in Peking University Third Hospital (hereinafter referred to “the operating room”).

## 2. The organizational environment

Peking University Third Hospital (PUTH) was founded in 1958 under the supervision of the Ministry of Health. Since that time, it has become a modern comprehensive upper first-class

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Peer review under responsibility of Chinese Nursing Association.

<http://dx.doi.org/10.1016/j.ijnss.2015.10.007>

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hospital which integrates medical services with medical education/teaching functions, and conducts research and prevention studies in addition to providing health care. The hospital currently has a staff of 2447 individuals, and contains 1463 clinic beds, 34 clinical departments, and 10 medical technique departments. In 2012, the hospital admitted >3.500 million outpatients and emergency visits, discharged >70,000 patients, and was the site of >44,000 operations. The average length of patient stay was 6.62 days. The overall quality of hospital management has reached an advanced level, as evidenced by the fact that the “Collaborative Optimization and Efficient Management of Key Resources in the Operating Room” project sponsored by the China Hospital Association awarded Peking University Third Hospital third prize for technological innovation.

PTUH has 42 operating rooms and employs 130 operating room nurses; however, during the last 10 years, the number of surgical patients at our hospital has increased on a yearly basis. Additionally, >33% of our hospitalized patients have an incurable disease. With the rapid development of new surgical techniques and use of high-tech equipment, the traditional methods used for managing operating room personnel no longer meet the needs of modern surgery and the increasing demand for medical services. Greater attention must be given to reducing operation table turnaround times, shortening the average patient stay, and increasing the quantity of surgery. Achieving these goals represents a challenge to operating room nursing management, but also presents opportunities for professional development. While operating room nurses have been traditionally managed based on their experience, they should now be managed using more modern methods. This change makes risk management an important tool for use in the operating room. Our hospital has established a specific committee (“Safe Operation Management Committee of the Operating Room”) that is mainly responsible for the safe operation of the operating room. Two types of risks (external and internal) currently threaten our hospital's operating room. One external risk is the constant yearly increase in the number of surgical patients. From 2005 to the end of 2012, the number of patients who underwent surgery at our hospital increased by 90%. Furthermore, 88% of the cases involved common surgery. Our hospital has 3 emergency operation tables and 39 common operation tables. If a major incident (e.g. an accident involving >5 people) were to occur during normal working hours when all of the common operation tables are occupied, it would be extremely difficult to schedule the needed operations. An example of an internal risk can be found by examining changes in operation table handover times. The handover time for an operation table has been shortened from 60 min in 2005 to 30 min in 2012. If proper operating room management is not in place, there is a greater chance that the enhanced efficiency demonstrated in the operating room will at the same time affect the safety of surgical patients. For example, a surgery may be performed incorrectly, the identity of a patient or patient specimen may be mistaking, or some type of medical accident may occur which will injure a patient, damage the hospital's reputation, and result in economic losses to the hospital.

The AS/NZS 4360 risk management standard is the first national risk management standard in the world, and was

jointly developed by Australia and New Zealand to satisfy both country's standards. It has currently been adopted by the Australian government, as well as several other countries. The AS/NZS 4360 standardizes the procedures followed and processes used in risk management, and thus effectively guarantees their ultimate effect. Furthermore, AS/NZS 4360 has become the benchmark for imitation throughout the world [2,3]. We applied the risk management process described in AS/NZS 4360 (Fig. 1) to functions performed in the operating room, and after consulting with operating room management concerning its individual components, we developed an operating room risk management plan (Fig. 2).

### 3. Risk management

#### 3.1. Establish the environment

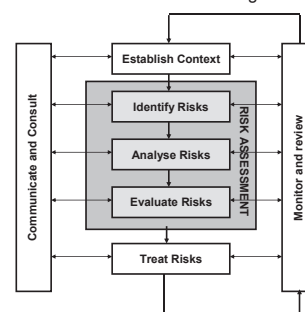
A risk management system should be implemented using a strategy suitable for the environment of the targeted institution. The establishment of the environment set the range for the rest of the risk management process [4]. An operating room risk management system must first be supported by both the internal and external management of a hospital, and be perceived as supporting the hospital's functions.

##### 3.1.1. Establish the strategic environment

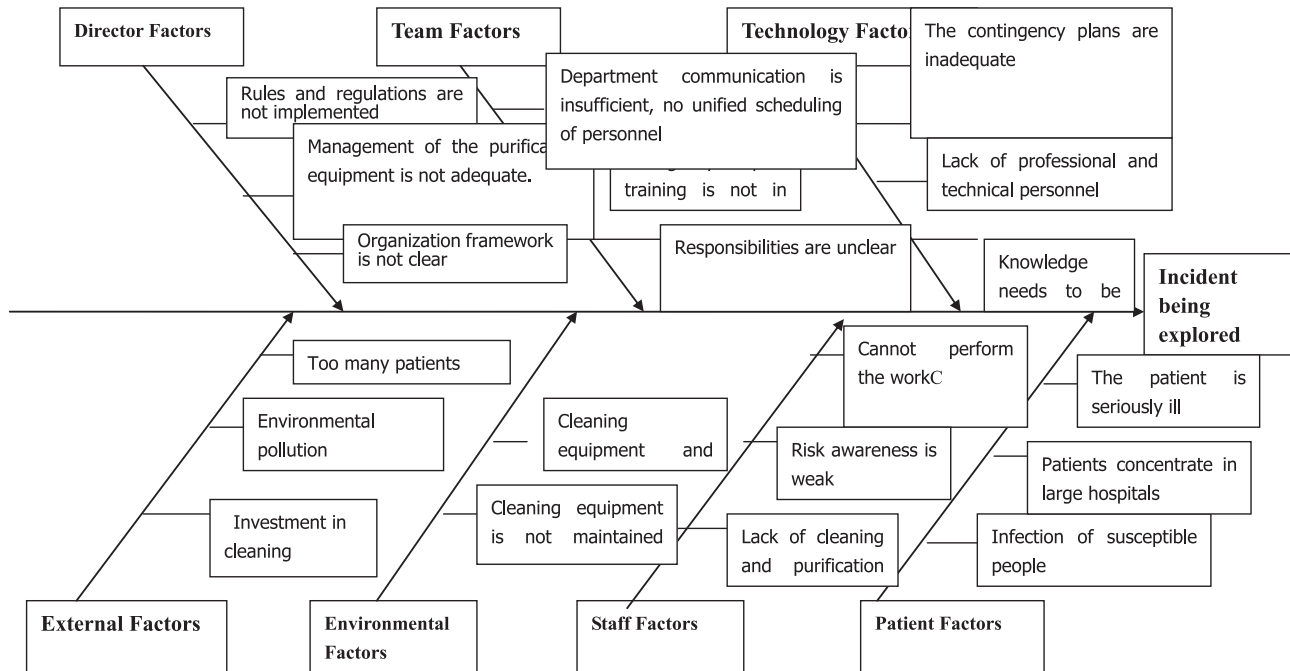
The operating room is a resource-intensive and key department of any hospital, and should provide service to patients under the unified leadership of numerous departments. As described by the original “Operating Room Safe Operation Management Committee,” which has the Medical Treatment President as its Director, the hospital was charged with establishing an “Operating Room Risk Management Committee” which included the Department Heads of Anesthesiology, Medicine, the Information and Equipment Center, Infection Management, the Operating Room, Nursing Department, and Logistics Service Center. These individuals are responsible for organizational leadership and making important decisions. The risk management committee consists of several “risk groups” derived from the above departments. Each Department Head is responsible for the risk management tasks associated with their own department in the operating room,

#### Risk management process

AS/NZS 4360:2004 - Risk management



**Fig. 1 – Risk management process. AS/NZS 4360:2004 – risk management.**



**Fig. 2 – System factors contributing to adverse events.**

and the personnel of each department are responsible for the risk management tasks associated with their own particular function.

### 3.1.2. Establishing the organizational environment

When established an operating room risk management system, a hospital should form an “operating room internal risk management group” composed of the Nursing Director, the Head Nurse of the operating room, the Head Nurse, and professional team leaders to be responsible for risk management procedures followed in the operating room. This group should also assess potential risk factors in the operating room, complete a risk assessment form, and develop emergency plans and work procedures.

### 3.1.3. Establishing the risk management principle

It is important to establish the following risk management principle in the operating room: “prevention first, everyone involved, and check erroneous ideas at the outset.” This principle will re-enforce the concept of a “safety culture,” and incorporate the concept of risk management into the various types of work performed in the operating room.

### 3.1.4. Establish a risk management responsibility system as well as a rewards and punishment system

The responsibility for carrying out tasks related to the risk management system must be clearly established at all levels. The Director of the “Operating Room Risk Management Committee” should be the main person responsible for risk management; however, each group leader is responsible for managing their own set of functions, and the personnel assigned each specific task must take direct responsibility for properly completing it. When an accident occurs, we should first examine the risk prevention system used for the entire




operating room, and then identify who is responsible for completing each required task. Awards should be given to operating room staff members who work to eliminate errors and make reasonable suggestions for improving the operating room risk management system.

### 3.1.5. Establish standardized systems for risk evaluation and risk identification

Any standardized system used for risk evaluation should comply with relevant provisions of State regulations. The order of the People's Republic of China regarding management of medical waste (management ordinance no. 380) describes current regulations concerning the following subjects: (1) the supervision and administration of medical devices (no. 276), and management of the hospital surgical department (room) (on trial) (WYZF [2009] 90); (2) management of hospital site infections (on trial) (WYF [2000] 431); (3) technical specifications for clinical blood transfusions (WYF [2000] 184); (4) technical specifications for endoscope cleaning and disinfection (2004 edition); (5) medical personnel hand hygiene norms WS/T313-2009; (6) technical specifications for disinfection and isolation WS/T31; (7) hospital infection monitoring norms WS/T312-2009; (8) norms for managing the hospital disinfection supply center and operation security verification system (WBYZF [2010] 41), etc. When the regulations in management order 380 are combined with the hospital's working instructions and procedures, the risks found in our operating room could be divided into 9 separate types: management risk; environmental risk; patient safety risk; IT risk; human resources risk; infection risk; occupational safety risk; legal risk; reputation risk. Furthermore, these risks could be divided into 4 levels based on their likelihood of occurrence and the severity of their consequences: low risk; moderate risk; high risk; extreme risk, as well as 3 categories consisting of:

**Table 1 – Risk quantification matrix.**

Consequence Likelihood	Insignificant 1	Minor 2	Moderate 3	Major 4	Extreme 5
Almost certain - 5	5	10	15	20	25
Likely - 4	4	8	12	16	20
Possible - 3	3	6	9	12	15
Unlikely - 2	2	4	6	8	10
Remote - 1	1	1	3	4	5

High  Low  Medium 

acceptable; reducible; unacceptable. We next identified some risks that should be analyzed, and reduced or eliminated. These included risks related to operation site marking, flammable and explosive gases, computer networks, operation room equipment, and personnel.

### 3.2. Risk identification

Based on 9 types of identified risks and the key elements described in Section 3.1.5, various methods including audit checks, brainstorming, informal discussions, group discussions, reviews of current and previous data, accident reporting, causal identification, and development of a standardized reporting check list were used to identify existing or potential risks in an operating room, and then conduct risk analysis and risk elimination procedures in a subsequent step.

### 3.3. Risk analysis

We analyzed the consequences of 10 risks in our Risk Register by using the Risk Quantification Matrix shown in Table 1. In

the 21st century, risks can be found everywhere, and include a terrorist attack, earthquake, tsunami, emergency public health events, and SARS, etc. Any large hospital should have the ability to deal with these various emergencies. Although our hospital has 3 emergency operating rooms and 39 common operating rooms available during normal working days, it can still be difficult to deal with sudden and unexpected events. Moreover, if >5 patients require surgery at the same time and the common operating tables are occupied, it may be unclear how to properly allocate the remaining tables. In 2005, our hospital implemented a clean operating room policy; however, it is not easy to maintain clean equipment throughout an entire normal operation. Consequence analyses for the ID1 and ID2 risks in the risk register are shown in Tables 2 and 3. Consequences were divided into categories of insignificant (category 1), minor (category 2), moderate (category 3), major (category 4), and extreme (category 5), based on their seriousness and potential costs. The likelihood that a risk event will actually occur is described in Table 4. The probability of occurrence can be divided into categories of remote (1), unlikely (2), possible (3), likely (4) and almost

**Table 2 – Qualitative estimates of the number of patients needing surgery in an operating room following a major incident.**

Level	Descriptor	Description
1	Extreme	Public emergency, >20 patients need surgical treatment at the same time.
2	Major	Public emergency, 15 patients need surgical treatment at the same time.
3	Moderate	Public emergency, 10 patients need surgical treatment at the same time.
4	Minor	Public emergency, 5 patients need surgical treatment at the same time.
5	Insignificant	Public emergency, 3 patients need surgical treatment at the same time.

**Table 3 – Qualitative estimates of consequences of infection accidents in the operating room.**

Level	Descriptor	Description
1	Extreme	Surgical site infection in >3 cases; SSI incidence > 0.5%.
2	Major	Surgical site infection in >3 cases; SSI incidence < 0.5%.
3	Moderate	Surgical site infection in 3 cases; SSI incidence < 0.5%.
4	Minor	Surgical site infection in 2 cases; SSI incidence < 0.5%.
5	Insignificant	Surgical site infection in 1 case; SSI incidence < 0.5%.

**Table 4 – Qualitative estimates of likelihood.**

Level	Descriptor	Description
5	Almost certain	It will happen in the vast majority of cases.
4	Likely	It will happen in a majority of cases.
3	Possible	It will happen in some cases.
2	Unlikely	It will happen in a few cases.
1	Remote	It will happen only in a particular type of case.

certain (5). The overall risk associated with an event is calculated by multiplying the consequence score by the likelihood score. When using this process, scores of 1–5, 6–15, and >16 signify low, moderate and major risks, respectively.

### 3.4. Risk assessment

The risk analysis described in Section 3.3 (see Risk Register) and the risk evaluation system described in Section 3.1.5, can be used to determine whether a risk is acceptable or needs to be eliminated. Risks deemed to be low or acceptable may only need to be minimized via simultaneous monitoring and regular checking, while risks deemed to unacceptable need to be eliminated or avoided. We established a Risk Register based on these criteria. Table 1 shows how internal and external factors can be used to analyze risks ID1 and ID2 listed in the Risk Register (Table 5).

### 3.5. Risk elimination

A brief description of various risks, their likelihood of occurrence, appropriate risk reduction strategies, and the parties responsible for implementing those strategies are summarized below in a Risk Treatment Plan (Table 6).

### 3.6. Establish a communication and consultation mechanism

Risk communication and consultation are important methods for managing risk. An effective communication and consulting system lays the foundation for risk identification, analysis, elimination, and employee feedback. Communication within the operating room not only involves communication between various departments and sections, but also with internal employees. Risk management requires everyone's participation, and thus it is necessary to continually improve

**Table 5 – Risk register.**

Risk ID	Risk Type	Risk Description	'Actual' or 'Potential' risk?	Consequences	Likelihood	Initial Risk Rating	Ranking
1	Business risk	Public emergency; > 5 patients from a car accident need surgical treatment at the same time during a normal working day.	P	5	4	20	1
2	Physical resource risk	Purification equipment in a clean operating room is not been properly maintained, resulting in serious nosocomial infections.	P	5	5	25	1
3	Physical resource risk	Incorrect use of electrosurgery equipment during an operation has resulted in patients being burned.	P	5	4	20	1
4	Patient care and safety	Patients develop pressure ulcers following surgery.	A	3	3	9	2
5	Patient care and safety	Paired organs are not marked prior to surgery, resulting in operative site errors.	P	5	4	20	1
6	IT Risk	The operating room information system is attacked by hackers, and physiological parameters cannot be monitored during an operation.	P	4	4	16	1
7	IT Risk	The operating room information system displays a patient's personal information, resulting in a violation of privacy rules.	P	4	3	12	2
8	Patient care and safety	The handover of the surgical specimens does not go smoothly, resulting in their damage or loss.	P	5	4	20	1
9	Human resource risk	A nurse experiencing severe personal problems, such as a disappointing love affair, makes a significant medical error at work.	A	5	4	20	1
10	Occupational safety	A nurse experiences a needle stick during an operation on a patient with hepatitis B.	A	5	3	15	2



the training of staff members regarding their knowledge of risks, and solicit their opinion regarding risk management. Additionally, it is necessary to communicate with higher level departments, and attempt to analyze and eliminate risk factors encountered in daily work in accordance with the “risk register” concept.

### 3.7. Establish a monitoring and evaluation mechanism

Risk management is a process of continuous improvement; thus it is necessary to periodically monitor and review the results of any new risk management system. Such reviews help to identify any residual risks, evaluate the progress of the risk management/control plan, and make continuous adjustments needed to improve risk management in the operating room. The operating room Risk Management Committee should hold a risk management conference each quarter to urge all departments to implement their respective plans related to the operating room. Furthermore, each department should hold a risk management work conference each month,

and the nursing department should review risks associated with assisting in operations, and summarize their findings in a monthly report. Finally, an adverse event reporting system that does not involve punishment should be established to complete a virtuous circle of risk management.

## 4. An evaluation of the AS/NZS 4360 standard

The AS/NZS 4360 standard mainly lists a set of definitions, and describes some standard processes used in risk management [5]. Additionally, it provides a theoretical framework for how each industry in each country can implement a risk management program. After studying the AS/NZS 4360 standard, I believe it provides both a theoretical basis for how the Chinese medical system can implement risk management, and at the same helps promote implementation of risk management in health care industry. The AS/NZS 4360 standard describes a new management concept. China has not previously

**Table 6 – Risk treatment plan.**

Risk ID	Risk Description	Implementation of risk reduction strategies	Time Table	Responsibility for action	Residual risk			
					Consequences	Likelihood	Initial Risk Rating	Ranking
1	Public emergency; > 5 patients in a car accident need surgical treatment at the same time during a normal working day.	(1) Activate the department emergency plan and emergency processes for sudden events, and constantly improve them. (2) Establish a green channel for unified deployment of manpower and operating rooms. (3) Strengthen communication and teamwork between each surgery department. (4) Conduct training and simulation exercises on a regular basis. (5) Establish emergency storage of surgical instruments and drugs.	Long-term approach	The Medical Department Risk Management Committee	5	3	15	2
2	Purification equipment in the clean operating room is not properly maintained, resulting in serious nosocomial infections.	(1) Specify the department responsible for purification equipment, and develop management rules and regulations. (2) Make professional and technical personnel responsible for the maintenance of cleaning equipment. (3) Immediately notify the operating room nurses about equipment problems. (4) Be sure the infection control staff test air quality in the operating room on a regular basis. (5) Regularly invite a third party supervisory institution (e.g. the national CDC) to inspect purification equipment.	Long-term approach	Office of General Services; The Infection Management office; The operating room	5	1	5	3
3	Incorrect use of electrosurgery equipment during an operation results in patients being burned,	(1) Perfect the procedures followed when using electric surgical equipment, and establish a standardized operation mode. (2) Improve the training of personnel who use electrosurgery equipment. (3) Improve the equipment maintenance and management procedures.	Long-term approach	The operating room and the Equipment Department	5	1	5	3
4	Patients develop pressure ulcers following surgery.	(1) Strengthen the risk assessment of pressure ulcers in surgical patients. (2) Develop a process for preventing pressure ulcers. (3) Purchase articles that can protect against pressure sores. (4) Improve personnel training.	Long-term approach	The operating room	3	1	3	3

5	Paired organs are not marked prior to surgery, resulting in operative site errors.	(1) Implement a strictly enforced surgical site marking system. (2) Implement use of a surgical safety checklist. (3) Strengthen personnel training. (4) Conduct regular audits.	Long-term approach	The Medical Department and each surgical department	5	1	5	3
6	The operating room information system is attacked by hackers, and physiological parameters cannot be monitored during an operation.	(1) Establish contingency plans. (2) Strengthen personnel training and conduct simulation drills on a regular basis. (3) Install manual measurement equipment. (4) Improve the hospital information system's ability to defend against hacker attacks.	Immediately	The Information Center; The operating room; The Anesthesia Department	4	1	4	3
7	The operating room information system displays a patient's personal information, resulting in a violation of privacy rules.	(1) Perfect the patient information system used in the operating room. (2) Only display a patient's medical registration number to family members in the waiting area.	Immediately	The Information Center and the Medical Department	4	1	4	3
8	The handover of surgical specimens does not go smoothly, resulting in their damage or loss.	(1) Improve the surgical specimen handover process. (2) Clarify the responsibilities of personnel involved in each link of the handover process. (3) Do not immediately hand over specimens for testing. (4) Improve personnel training and supervision.	Immediately	The operating room and the Pathology Department	5	1	5	3
9	A nurse experiencing severe personal problems, such as a disappointing love affair, makes a significant medical error at work.	(1) Encourage managers to improve their communication with nurses, and provide psychological guidance. (2) Change the nursing assignments. (3) Holiday adjustment.	Immediately	The operating room	5	1	5	3
10	A nurse experiences a needle stick during an operation on a patient with hepatitis-B.	(1) Improve training for prevention of occupational exposure. (2) Strengthen protection measures. (3) Establish a standard procedure for passing sharp instruments during an operation.	Immediately	The operating room	5	1	5	3

developed its own quantitative risk management evaluation system, and thus AS/NZS 4360 represents the risk management reference standard for the Chinese medical industry. It provides a list of quantitative tools for risk identification, risk analysis, and risk management that can be used in clinical practice, including the hospital operating room. Implementation of the concepts described in AS/NZS 4360, allowed us to establish a risk management plan with monitoring and evaluation systems, as well as channels for communication, consultation, and feedback that can help to avoid major accidents. However, China should not simply copy the existing AS/NZS 4360 and use it in standard practice, because it must first be modified to be applicable to the specific situations found in China. Different institutions in China face different types of risks, and must take different approaches when seeking to eliminate or control them.

In short, an operating room risk management program should identify, analyze, and eliminate actual and potential risks. It should also establish communication, consultation, monitoring, and review mechanisms that assist in risk

prevention, and facilitate the continuous improvement of risk management capabilities.

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